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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,858	12/12/2005	Daniel Raederstorff	21478USWO (C038435/0187	7897

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EXAMINER	
MCCORMICK, MELENIE LEE	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/533,858	RAEDERSTORFF ET AL.	
	Examiner	Art Unit	
	Melenie McCormick	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 20-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 and 20-24 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 20 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating type I and type II diabetes, impaired glucose tolerance or obesity does not reasonably provide enablement for prevention of diabetes impaired glucose tolerance and obesity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants have reasonably described/disclosed that the instantly claimed composition comprising EGCG and at least one of pantethine or phytanic acid and method of making such a composition is useful for treating diabetes, impaired glucose tolerance or obesity. However, the claims (see e.g. claim 1) encompass using the claimed composition and method for preventing such conditions. Please note that the term "prevent" is an absolute definition which requires a higher standard for enablement than does "treating", especially since it is well known in the medical art that the vast majority of medical conditions are not able to be prevented. Please note that, as

referenced by diabetes.org, the cause of diabetes remains a mystery. Therefore, one of skill in the art would not be able to prevent diabetes using the instantly claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 20 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-13 of copending Application No. 10/766,118. Although the conflicting claims are not identical, they are not patentably distinct because each are drawn to a method of treating non-insulin dependent diabetes comprising administering to a subject in need a composition which comprises phytanic acid.

Claims 21-24 are provisionally rejected as being unpatentable over claims 1-2, 4, 7-18 of copending Application No. 10/573,222 because each are drawn to a method of making a nutraceutical composition for the treatment or prevention of diabetes comprising phytanic acid and EGCG.

Claims 1-14 are provisionally rejected as being unpatentable over claims 1-8 of copending Application No. 10/558,042 because each are drawn to compositions comprising EGCG.

Claims 1-14 and 20-24 are rejected as being unpatentable over claims 1-9 of copending Application No. 10/536,374 because both are drawn to a composition comprising EGCG for treatment of diabetes, a method of making the composition and a method of treatment of diabetes using the composition.

Claims 1-14, 20,and 22-24 are rejected as being unpatentable over claims 1-8, 18-20 and 26-27 of copending Application No. 10/525,348 because each are drawn to a composition comprising at least one of EGCG, phytanic acid, pantethine, lipoic acid and policosanol and a method for the treatment of diabetes comprising administering to a subject in need thereof such a composition.

Further, please note that the claims of '118, '222, 042, '374, '348 encompass and/or are encompassed by the instant claims.

The above rejections are provisional obvious-type double patenting rejections because the conflicting claims have in fact not been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Gorsek (US 6,565,896).

A composition comprising EGCG and pantethine is claimed.

Gorsek teaches a composition which comprises EGCG and pantethine (see e.g. claim 1).

With respect to the art rejection above; it is noted that the reference does not teach that the composition can be used in the manner instantly claimed (i.e. as a treatment for diabetes, obesity or glucose intolerance), however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan (US 5,922,756), Fluehmann et al. (US 6,784,207), and Cincotta et al. (US 5,714,519).

A composition comprising EGCG and at least one of pantethine and phytanic acid, a method of making the composition, and a method of treatment of type II diabetes comprising administering to a subject in need thereof a composition comprising EGCG and pantethine and phytanic acid is claimed.

Chan beneficially teaches that EGCG is an inhibitor of nitric oxide synthase (see e.g. col. 3, lines 23-25). Chan further teaches that an NO synthase may be involved in diabetes and therefore, catechin derivative (including EGCG) may be helpful in treating the condition (see e.g. col 3, lines 51-56). Chan also beneficially teaches a method of treating diabetes which comprises administering to a mammal in need thereof EGCG (See e.g. claims 1, 2, and 7). Chan further teaches that EGCG is in a pharmaceutical formulation presented in discrete unit dosages and that the discrete unit dosages may be capsules or tablets (solid unit dosages) (see e.g. col 4, lines 18-34). Chan also

teaches that the EGCG is administered in a dose of 50 mg to 17.5 grams/day, which is within the dose range instantly claimed (see e.g. claim 6). Chan does not explicitly teach that phytanic acid or pantethine are included in this composition.

Fluehmann et al. beneficially teach a composition for the treatment of diabetes comprising phytanic acid, a method of making the composition (see e.g. col 6, lines 1-5) and a method for the treatment of diabetes using phytanic acid (see e.g. col 1, lines 11-15). Fluehmann et al. also beneficially teach that the composition is in a unit dosage form, such as tablets or capsules (solid dosage forms) (see e.g. col 7, lines 57-61). Fluehmann et al. further teach that the amount of phytanic acid administered is within the dose range instantly claimed (about 0.1 to about 1000 mg, about 0.1 to about 500 mg or about 0.1 to 100 mg) (see e.g. claims 1, 4 and 5).

Cincotta et al. beneficially teach a method for the treatment of diabetes comprising administering to a subject in need thereof an effective amount of pantethine (see e.g. col 4, lines 26-34). Cincotta et al. also disclose that the dose range intended for use with this method is between 15 to about 500 mg/kg of body weight per day, which is within the dose range instantly claimed (see e.g. col 5, lines 6-11 and claim 5).

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to admix EGCG, pantethine, phytanic acid and mixtures thereof in the dosage forms and amounts instantly claimed in order to make a composition for the treatment of diabetes. One of ordinary skill in the art would have been motivated to so based upon the disclosures of Chan, Fluehmann et al., and Cincotta et al. that EGCG, phytanic acid and pantethine are useful in the treatment of

diabetes in the same ranges of dose amounts and in the same forms instantly claimed. It would further have been obvious to administer such a composition to a subject in need of treatment for diabetes, especially in view of the disclosure of methods for treatment disclosed by Chan, Fluehmann et al., and Cincotta et al. which comprise administration of each component of the instantly claimed composition to a subject in need of diabetes treatment. The adjustment of particular conventional working conditions (e.g. the particular result effective amounts of each component within the composition and the addition of the composition to a food or beverage) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chan (US 5,922,756), Fluehmann et al. (US 6,784,207), Cincotta et al. (US 5,714,519), Fischer (US 5,599,835), Pistolesi (WO 02/052955 A1) and Eriksson et al. (BioFactors).

Chan (US 5,922,756), Fluehmann et al. (US 6,784,207), and Cincotta et al. (US 5,714,519) beneficially teach composition and methods for the treatment of diabetes comprising EGCG, phytanic acid and pantethine and are relied upon for the reasons set forth above.

Fischer (US 5,599,835) beneficially teaches lipoic acid as a treatment for diabetes (see e.g. abstract). Fischer further teaches a method for the treatment of diabetes comprising administering to a person in need thereof an effective amount of a medicinal food comprising lipoic acid (see e.g. claim 1).

Pistolesi beneficially teaches a composition for treating aging processes and related compositions, including diabetes. Pistolesi further teaches that the composition comprises policosanol (see e.g. page 1). Pistolesi also discloses that the composition may be used in functional foodstuffs (see e.g. claim 19).

Eriksson beneficially teaches the use of coenzyme Q_{10} in a treatment for diabetes (see entire document and Discussion).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the ingredients beneficially taught by Chan, Fluehmann et al., Cincotta et al., Fischer, Pistolesi, and Eriksson to make a food or beverage comprising EGCG, pantethine, phytanic acid, lipoic acid, policosanol and coenzyme Q_{10}. A person of ordinary skill in the art would have been motivated to combine these ingredients because, as discussed above and in the instantly cited references, the use of these compounds for the same purpose (treatment of diabetes) was known at the time the claimed invention was made. A person of ordinary skill in the art would have further been motivated to add the composition to a food or beverage since this is a widely known modification in the nutritional supplement art and since it is disclosed by Fischer and Pistolesi that a diabetes treatment is in the form of a food.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CHRISTOPHER R. TATE
PRIMARY EXAMINER